

**U.S.S.N. 09/135,988**

**BRYAN  
AMENDMENT**

Claims 1-5, 11-19, 30-32, 46, 47 and 55-97 are presently pending.

Claims 1, 2, 47, and 60-66 are amended herein to correct obvious typographical errors or to cancel subject matter that has issued in the parent application.

Claim 10, which is withdrawn from consideration as being drawn to non-elected subject matter, is cancelled herein. Claim 69-94, which find particular basis in the specification as originally filed, are added herein.

Claims 2, 60 and 61 are objected to as being dependent upon a rejected base claim and would be allowable if rewritten as independent claims or as dependent upon an allowable base claim. Claim 2 has been rewritten as an independent claim and claims 60 and 61 amended to depend thereon. Hence claims 2, 60 and 61 should be allowable. In addition, claims 71 and 75-96, which ultimately depend from claim 2, which has been deemed allowable, should also be allowable. As the arguments and remarks below demonstrate, claim 1 and its dependents should also be allowable.

**THE REJECTION OF CLAIMS 1, 3-5, 11-19, 30-32, 46, 47, 59 AND 62-68  
UNDER 35 U.S.C. §103(a)**

Claims 1, 3-5, 11-19, 30-32, 46, 47, 59 and 62-68 are rejected under 35 U.S.C. §103(a) as being unpatentable over Lloyd *et al.* in view of "common knowledge" because Lloyd *et al.* allegedly teaches an apron made of luminescent material, and "bioluminescent compositions and methods of applying them are notoriously well known." The Examiner concludes it would have been obvious to one of ordinary skill in the art to have applied known bioluminescence compositions to the apron of Lloyd *et al.* "with the expectation of making a suitable product." The Examiner states that motivation might be to use "the bioluminescent host cell to also overproduce and secrete cellulose-degrading enzymes, thus making a self-biodegrading product."

This rejection is respectfully traversed.

**Relevant law**

In order to set forth a prima facie case of obviousness under 35 U.S.C. §103: (1) there must be some teaching, suggestion or incentive supporting the

*B*

**U.S.S.N. 09/135,988**

**BRYAN  
AMENDMENT**

combination of cited references to produce the claimed invention (ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 USPQ 329, 933 (Fed. Cir. 1984)) and (2) the combination of the cited references must actually teach or suggest the claimed invention. Further, that which is within the capabilities of one skilled in the art is not synonymous with that which is obvious. Ex parte Gerlach, 212 USPQ 471 (Bd. APP. 1980). Obviousness is tested by "what the combined teachings of the references would have suggested to those of ordinary skill in the art" In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981), but it cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination (ACS Hosp. Systems, Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577, 221 USPQ 329, 933 (Fed. Cir. 1984)). "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher" W.L. Gore & Associates, Inc. v. Garlock Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983).

The prior art must provide a motivation whereby one of ordinary skill in the art would have been led to do that which the applicant has done. Stratoflex Inc. v Aeroquip Corp., 713 F.2d 1530, 1535, 218 USPQ 871, 876 (Fed. Cir. 1983). In addition, the mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification. In re Fritch, 23 USPQ 1783 (Fed. Cir. 1992).

Also, it is impermissible to ignore the advantages, properties, utilities and unexpected results that flow from the claimed invention; they are part of the invention as a whole. In re Sernaker, 702 F.2d 989, 217 USPQ 1 (Fed. Cir. 1983). Unexpected properties must always be considered when determining

**U.S.S.N. 09/135,988**

**BRYAN  
AMENDMENT**

obviousness. A compound's structure and properties are inseparable so that unexpected properties are part of the subject matter as a whole. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

**The claims**

The claims are directed to **novelty items** that comprise a combination of an article of manufacture with a bioluminescence generating system. As defined in the application, a bioluminescence generating systems is defined as follows (see page 21, line 15, - page 22, line 5):

As used herein, bioluminescence system [or bioluminescence generating system] refers to the set of reagents required for a bioluminescence-producing reaction. Thus, the particular luciferase, luciferin and other substrates, solvents and other reagents that may be required to complete a bioluminescent reaction form a bioluminescence system. Therefore, a bioluminescence system (or equivalently a bioluminescence generating system) refers to any set of reagents that, under appropriate reaction conditions, yield bioluminescence.

Also as defined in the application:

As used herein, novelty items refer to inanimate articles of manufacture that are intended to provide, even for only a few moments, amusement, entertainment, decoration or recreation. The use for recreation or entertainment may be the items only use or may be in addition to other uses or benefits of the items, such as clothing that is modified, as described herein, by combination with bioluminescence.

Hence the claims are directed to combinations of at least one component of the "the set of reagents required for a bioluminescence-producing reaction and an article of manufacture such that the resulting item is a novelty item, which is an item "intended to provide, even for only a few moments, amusement, entertainment, decoration or recreation."

**Differences between the teachings of the cited reference and claimed subject matter**

The reference, singly or in combination with the alleged knowledge of the art, neither teaches nor suggests a novelty item that comprises an article of manufacture and at least one component of a bioluminescence generating system.

U.S.S.N. 09/135,988

BRYAN  
AMENDMENT

**Lloyd et al.**

Lloyd *et al.* teaches a disposable paper apron that has integral sleeves and mittens and that has shoulder extensions so that apron does not restrict the movements of the wearer. The apron is intended to be worn outside including in the cold (hence the mittens) to protect the clothes of the wearer. In one embodiment, the apron may be made of light reflective material, such as luminescent or phosphorescent material to render the wearer visible in the dark.

The apron of Lloyd *et al.* is not a novelty item; it is intended to protect the clothes of the wearer and, for the embodiments in which the apron includes reflective material, it is to make the wearer visible, such as when changing a tire by the side of the road at night.

A reflective coating as described by Lloyd *et al.* does not generate its own light, but rather reflects light shown upon it (hence the term "reflective.") Reflective material, such as phosphorescent material does not require a reaction to occur to generate light, but inherently possesses the ability to reflect light and glow in the dark. Furthermore, reflective material will reflect light for as long as the apron is worn; the light will not dissipate because a reaction as used up the reagents. As noted in the application, bioluminescence reactions require the mixture of reagents to produce a reaction that lasts from a few minutes up to an hour or so, depending upon the system and the amounts of the reagents.

Lloyd *et al.* does not teach or suggest using bioluminescence in place of a reflective coating, and particularly does not suggest inclusion of at least one component of a bioluminescence generating system.

**Examiner's statements of general knowledge in the art**

The Examiner states that:

bioluminescent compositions and methods of applying them are notoriously well known.

No evidence to support this statement is provided.

**U.S.S.N. 09/135,988**

**BRYAN  
AMENDMENT**

The Examiner also states that:

[m]motivation might be to use the bioluminescent host cell to also overproduce and secrete cellulose-degrading enzymes, thus making a self-biodegrading product.

No support for these allegation is provided.

MPEP 2144.03 states:

The Examiner may take official notice of facts outside of the record which are capable of instant and unquestionable demonstration as being "well-known" in the art. In re Ahlert, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970). . . .

The properties ascribed by the Examiner to bioluminescence are not "capable of instant and unquestionable demonstration as being "well-known" in the art. The Examiner has not cited any art that demonstrates combinations of bioluminescence generating systems for non-analytical uses.

MPEP 2144.03 continues:

If justified, the examiner should not be obliged to spend time to produce documentary proof. If the knowledge is of such notorious character that official notice can be taken, it is sufficient so to state. In re Malcolm, 129 F.2d 529, 54 USPQ 235 (CCPA 1942). If the applicant traverses such an assertion the examiner should cite a reference in support of his or her position.

In this instance, there is no evidence that knowledge about the properties of bioluminescence are not of such notorious character that official notice can be taken. Furthermore, bioluminescence and its use are of a more esoteric nature, since it is used in analytical applications as reporters. For esoteric technology, MPEP 2144.03 states:

("[A]ssertions of technical facts in areas of esoteric technology must always be supported by citation of some reference work" and "allegations concerning specific 'knowledge' of the prior art, which might be peculiar to a particular art should also be supported." Furthermore the applicant must be given the opportunity to challenge the correctness of such assertions and allegations. "**The facts so noticed serve to 'fill the gaps' which might exist in the evidentiary showing" and should not comprise the principle evidence upon which a rejection is based.**). See also In re Barr, 444 F.2d 588, 170 USPQ 330 (CCPA 1971) (scientific journal references were not used as a basis for taking judicial notice that

**U.S.S.N. 09/135,988**

**BRYAN**

**AMENDMENT**

controverted phrases were art-recognized because the court was not sure that the meaning of the term at issue was indisputable among reasonable men); and *In re Eynde*, 480 F.2d 1364, 1370, 178 USPQ 470, 474 (CCPA 1973) ("The facts constituting the state of the art are normally subject to the possibility of rational disagreement among reasonable men and are not amenable to the taking of [judicial] notice.").

In this instance, the Examiner taking judicial notice provides the crux of the rejection. The Examiner is taking judicial notice of allegations key to the rejection and combining them with a reference that does not suggest or mention bioluminescence or novelty items, key elements of the claimed products.

Also, it is unclear to what host cells the Examiner refers. The claims do not specify host cells, nor does the cited art. As noted above, and with due respect, the concept proposed by the Examiner really does not make sense. Nowhere in the art of record is there a suggestion to combine the apron of Lloyd *et al.* with host organisms that generate bioluminescence; these aprons are intended to be used under harsh conditions (Lloyd *et al.* gives the example of the wearer changing a tire on the side of a road). It is unclear what organisms are contemplated and how they would function or be maintained under such conditions nor how the biodegrading activity would be initiated.

#### **Analysis**

First, although as noted in the application, bioluminescence reactions and systems are well known. Heretofore they have been used as analytical reagents. There is no art of record teaching the use of bioluminescence generating systems for novelty items. The light generated by bioluminescence generating reaction is brief, and not sustained. The statement that methods for applying bioluminescence generating compositions to articles of manufacture is well known, is not correct. The bioluminescence reaction is transitory (lasting from a few minutes to an hour or so). As a result, the components of the reaction must be kept separate until right before use and then in some manner mixed under the proper conditions to generate a reaction. Heretofore, the principle use of bioluminescence was as an analytical reagent under very

**U.S.S.N. 09/135,988**

**BRYAN  
AMENDMENT**

controlled conditions, not under the less controlled conditions that the instant application contemplates. Thus, it is not likely, nor is there evidence of record that the ordinarily skilled artisan, when selecting a means for illuminating an apron, would have selected bioluminescence. First, there is no evidence of record that the reaction would proceed on an apron outside. Second, after a few minutes or maybe an hour the reaction would be over leaving the wearer (who is changing a tire on the side of the road, for example) dark. Bioluminescence is not a logical choice to have selected it for use on an item worn to protect clothing and in the embodiments in which it is coated with reflective material, designed to render the wearer visible in the dark for safety purposes.

**The combination of teachings of the cited reference with the knowledge in the art does not result in the instantly claimed novelty items**

As noted above, the cited reference nor the alleged knowledge in the art, does not result in a combination that is a novelty item that includes an article of manufacture and a bioluminescence generating system.

First, as noted above, the bioluminescence reaction is not a sustained reaction, rather it typically lasts for a few minutes or up to an hour. The reaction must be initiated by a mixing or contacting of the reagents, so that the apron could not be coated with the bioluminescence generating system, but requires some means of separation of the reagents. Neither Lloyd *et al.* nor Lloyd *et al.* in combination with the knowledge in the art suggests an apron coated with a component of a bioluminescence generating system (as claimed in this application). There is no suggestion in the combined teachings for an apron coated with a luciferase or luciferin.

Second, coating the apron with a bioluminescence generating system does not substitute for a reflective coating. Not only is bioluminescence not a reflective coating, it is produced by a reaction that requires energy, once the components are spent, the reaction ends. Hence any glow that would render the wearer visible would not be sustained.

**U.S.S.N. 09/135,988**

**BRYAN  
AMENDMENT**

In addition, prior uses of bioluminescence are typically analytical under very controlled conditions. There is no suggestion that the reactions could reliably be generated under "field" conditions, such as those for which the apron of Lloyd *et al.* would be worn (changing a tire etc.). If the apron is designed to protect the clothing of the wearer from the environment, the conditions are not laboratory conditions.

Third, the apron of Lloyd *et al.* is not a novelty item; it is an item intended to protect the clothing of the wearer. The embodiments employing the reflective coating are for the purpose of rendering the wearer visible. This is not an item intended to provide, even for only a few moments, amusement, entertainment, decoration or recreation as defined in the instant application.

Therefore, the combined teachings of the art fails to teach or suggest critical elements of the claimed combinations. Among these elements are the requirement that the resulting item is a **novelty** item intended for amusement, entertainment, decoration or recreation. In addition, the art does not suggest combining an article of manufacture with a component of a bioluminescence generating system and then initiating a reaction by adding the remaining components to produce the glow.

Therefore, the combination of teachings does not result in the instantly claimed combinations that are novelty items.

**Motivation**

Second, the Examiner states that motivation may be to use host cells that also secrete biodegrading enzymes to make the product self-biodegradable. It is respectfully submitted that the "motivation" suggested by the Examiner is without basis in the cited art and is unrelated to what is claimed in the instant application and also what is disclosed in Lloyd *et al.* The Examiner urges that a motivation to combine a bioluminescence generating system with the apron of Lloyd *et al.* would be the desire to coat the apron with host cells that,

U.S.S.N. 09/135,988

BRYAN  
AMENDMENT

presumably not only produce bioluminescence, but also express a cellulose or other paper degradative enzyme so that the paper apron will be degraded.

One can only imagine putting on an apron, intended to protect the wearer's clothes, that is coated with glowing organisms (producing relatively short-lived bioluminescence) that also secrete enzymes that are degrading the apron. After a while the wearer's clothing is coated with the spent organisms and the remaining ooze of the enzymatically degraded apron. This hardly protects the wearer's clothes, and one can only hope the tire can be changed before the bioluminescence reaction is spent and the apron degraded.

The suggestion that motivation to combine host organisms them with the apron of Lloyd *et al.* derives from a desire to produce a biodegradable apron is without basis. Lloyd *et al.* is directed to a "disposable" apron. No mention of biodegradability is provided. Furthermore, coating the apron with organisms that secrete enzymes would result, not in a biodegradable apron, but in a biodegrading apron. As these organisms were producing bioluminescence they would be degrading the apron. Hence, the resulting product of Lloyd *et al.* would not be suitable for the purpose intended by Lloyd *et al.*.

Thus, there is no motivation provided in Lloyd *et al.* to have substituted a component of a bioluminescence generating system for the reflective coating taught by Lloyd *et al.* Such substitution would render the resulting article unsuitable for its intended purpose.

The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification. In re Fritch, 23 USPQ 1783 (Fed. Cir. 1992). In this instance, there is no suggestion of such modification nor the desirability thereof by the cited art. Therefore, because the combination of cited references does not result in the claimed subject matter, and because there would have been no motivation to have modified the product of the art that

**U.S.S.N. 09/135,988**  
**BRYAN**  
**AMENDMENT**

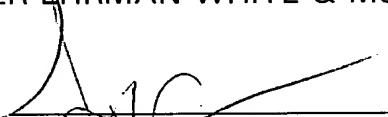
would result in the instantly claimed products, the Examiner has failed to set forth a prima facie case of obviousness.

\* \* \*

In view of the above amendments and remarks, reconsideration and allowance of the application are respectfully requested.

Respectfully submitted,  
HELLER EHRLMAN WHITE & McAULIFFE LLP

By:

  
Stephanie Seidman  
Registration No. 33,779

Attorney Docket No. 24729-105C  
**Address all correspondence to:**  
Heller Ehrman White & McAuliffe LLP  
4250 Executive Square, 7th Floor  
La Jolla, CA 92037  
Telephone: 858 450-8400  
Facsimile: 858 450:8499  
EMAIL: [sseidman@HEWM.com](mailto:sseidman@HEWM.com)